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APR 25 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Shimon Sakaguchi

Art Unit : 1632

TECH CENTER 1600/2900

Serial No. : 09/284,114

Examiner : Michael C. Wilson

Filed : April 7, 1999

Title : A MOUSE STRAIN WITH NATURAL ONSET OF AUTOIMMUNE
ARTHRITIS

Commissioner for Patents

P.O. Box 2327

Arlington, VA 22202

DECLARATION UNDER 37 C.F.R. §1.132

1. I, Shimon Sakaguchi, M.D., Ph. D., having an address at Shichiku Nishi-kurisu-cho 11-2, Kita-ku, Kyoto 603-8436, Japan, am the sole inventor of the above-referenced United States patent application serial no. 09/284,114. I am a professor of Experimental Pathology at the Institute for Frontier Medical Sciences, Kyoto University, and am an expert in the general fields of experimental pathology and immunology, particularly, in the field of arthritis.

2. On November 6, 2001, I deposited a stable strain of mice that developed rheumatoid arthritis with the International Patent Organism Depository National Institute of Advanced Industrial Sciences and Technology. The deposit, received on November 6, 2001, was accepted by the International Depository Authority and assigned accession number FERM BP-7790. A copy of the notification from a representative of the International Depository Authority acknowledging acceptance of the deposit is attached.

3. The deposited material is the same as that described in the specification on page 3, lines 6-7, see the reference to the SKG strain. The SKG strain was first described in Japanese priority application no. 267126/1996, filed October 8, 1996.

4. I submit that this strain is the same as that deposited on November 6, 2001, with the International Depository Authority. I believe this to be true because the offsprings from the crossings between the deposited strains developed rheumatoid arthritis.

For example,

a) In twenty offsprings from the crossings between the deposited strains, all twenty offsprings developed rheumatoid arthritis.

b) CLEA JAPAN, Inc. mated the SKG strains under my instructions. CLEA JAPAN, Inc. inducted ovulation of female mice and mated male mice and female mice to obtain embryos that were in two cells stage.

c) CLEA JAPAN, Inc. froze the embryos under my instructions as follows. The used tube was Nunc CryoTube 1.8ml No.363401.

Date	Number of embryos in a tube	No. of tube (tube color)
2001.9.7	23	4cf (purple)
	17	4f1 (purple)
	19	4f2 (purple)
	14	4f3 (purple)
	12	4fh (brown)
2001.9.14	12	4fi (brown)
	19	4fj (brown)
	15	4gi (red)
2001.9.21	15	4gj (red)
	15	4gk (red)
	16	4gil(red)
	17	4ii (yellow)
2001.10.12	12	4jj (yellow)
	19	4ik (yellow)
	14	4j8 (red)
2001.10.17	13	4j9 (red)
	22	4jA (orange)

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	22	4jB (orange)
2001.10.19	16	4jS (blue)
	16	4jT (blue)
	20	4jU (pink)
	19	4jV (pink)
2001.10.24	15	4K5 (red)
	15	4K6 (red)
	20	4K7 (red)
Total	417	25 tubes

Then the frozen tubes were sent to International Patent Organism Depository National Institute of Advanced Industrial Science and Technology on November 6, 2001 and received the accession number FERM BP-7790.

5. Accordingly, I submit that the deposited material, FERM BP-7790, was in our possession at the time of filing of the instant application and that the deposited material is the same material as that described in the specification as the SKG strain.

6. I also declare that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty, as evidenced by the attached notification; that all restrictions will be irrevocably removed upon the grant of a patent on this application; and that the deposit will be replaced if viable samples cannot be dispensed by the depository.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

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Date: April 15, 2003

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Respectfully Submitted

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Shimon Sakaguchi, M.D., Ph. D.

Professor

Department of Experimental

Pathology

Institute for Frontier Medical Sciences

Kyoto University

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